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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/920,871	08/02/2001	Robert L. Rykhus JR.	687-437	5424

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EXAMINER	
THALER, MICHAEL H	
ART UNIT	**PAPER NUMBER**
3731	

DATE MAILED: 08/03/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/920,871	RYKHUS ET AL.	
	Examiner	Art Unit	
	Michael Thaler	3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 June 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-57* is/are pending in the application.

4a) Of the above claim(s) *26-49* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-25 and 50-57* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on April 21, 2004 has been entered.

Claims 26-49 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made without traverse in Paper No. 8.

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: The upper limit of 75 kGy defined in claims 1 and 9 should be added to the specification.

Claims 52 and 53 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the

claimed invention. There is no basis in the original disclosure for the limitation that in the compressed state, the stent has a length that is twice a length, or more, of the stent in an expanded state.

Claims 17-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hogan (6,569,191) in view of Stack (WO 91/17789). Hogan discloses a bioabsorbable self-expanding stent (col. 5, lines 50-66) comprising a cylindrical sleeve (e.g. 21) including a latticed network formed from a plurality of monofilaments 22, 26 braided in an alternating braid pattern (col. 5, lines 49-50) which comprise at least one biocompatible polymer (col. 7, lines 45-50), said cylindrical sleeve having a limited in vivo lifetime (since it is bioabsorbable) which is controllable as indicated in col. 3, lines 20-23. Further, the in vivo lifetime is inherently "controllable" as claimed since it is controlled or determined at the time of manufacture by factors such as the size of the sleeve, the specific choice of bioabsorbable material, whether or not it is exposed to gamma radiation (and how much), noting that the Hogan stent is inherently capable of being exposed to gamma radiation. Hogan fails to disclose the stent as being annealed and gamma-irradiated. However, Stack teaches that the bioabsorbable filaments of a self-expanding stent should be annealed in order

to heat set them and thus insure that they will return to a helical form if distorted (page 26, lines 16-18). It would have been obvious to anneal the Hogan filaments so that the Hogan stent too would have this advantage. Further, Stack teaches that the bioabsorbable filaments of a self-expanding stent should be gamma-irradiated in order to control the rate that the stent degrades (page 19, lines 24-28). It would have been obvious to irradiate the Hogan filaments so that the Hogan stent too would have this advantage. As to claim 17, Hogan fails to disclose the specific number of monofilaments claimed. However, it was well known in this art to use a large number of filaments for a stent and to choose a number which optimizes the desired expansion force and size of the stent. It would have been obvious to use the specific number of monofilaments claimed for the Hogan stent so that it would have these advantages. As to claims 20-23 and 25, Hogan fails to disclose the specific diameter claimed. However, it was well known in this art to size stents as with the specific diameter claimed so that it fits a correspondingly sized blood vessel. It would have been obvious to size the Hogan stent as claimed so that it would have this advantage. The above well known in the art statements are taken to be admitted prior art because applicant failed to traverse the examiner's assertions (M.P.E.P. 2144.03). As to

the term "fenestrated" wall surface defined in claims 18 and 22-25, for example, the openings between the threads of the Hogan stent are fenestrations, making the wall "fenestrated", as broadly claimed. As to claim 19, Hogan discloses polydioxanone in col. 2, line 58.

Claims 1-3, 8-11, 16, 51 and 57 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hogan (6,569,191) in view of Stack (WO 91/17789) as applied to claims 17-25 above, and further in view of Cotterman et al. (2002/0153511). Hogan and Stack fail to disclose the amount of gamma irradiation of in the range of approximately 35 kGy to 75 kGy. However, Cotterman et al. teach that a stent ([0043]) should be irradiated with gamma irradiation in the amount of 39 kGy in order to sterilize it effectively ([0098]). It would have been obvious to irradiate the Hogan stent with this amount of gamma irradiation so that it too would be sterilized. As to claim 57, Hogan discloses poly-L-lactide in col. 2, line 55.

Claims 4 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hogan (6,569,191) in view of Stack (WO 91/17789) and Cotterman et al. (2002/0153511) as applied to claims 1 and 11 above, and further in view of Amstrup (5,476,508). Hogan fails to disclose a single strand shift in the braid. However, Amstrup teaches that braiding in a stent should

include a single strand shift (at 12) in order to interlock the weave and apparently guarantee a stable crossing region which can accept large restoring forces (col. 4, lines 7-21). It would have been obvious to include a single strand shift in the Hogan braid so that it too would have this advantage.

Claims 5-7 and 13-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hogan (6,569,191) in view of Stack (WO 91/17789) and Cotterman et al. (2002/0153511) as applied to claims 1 and 9 above, and further in view of Thompson et al. (5,957,974). Hogan fails to disclose the claimed braid angle. However, Thompson et al. teach that the braid angle for a self-expanding stent should be 60-150 and preferably 90-100 degrees (col. 7, lines 21-22) apparently in order to optimize the amount of shortening (col. 7, lines 24-35). It would have been obvious to use this braid angle in the Hogan braid so that it too would have this advantage.

Claim 50 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hogan (6,569,191) in view of Stack (WO 91/17789) as applied to claim 17 above, and further in view of Turnlund et al. (5,629,077). Hogan fails to disclose an under-two-over-two braid pattern. However, Turnlund et al. teach that the braid pattern for a stent should be under-two-over-two (col. 5, lines 54-56) apparently in order to obtain the desired

strength of the mesh (col. 6, lines 6-9). It would have been obvious to use this braid pattern in the Hogan stent so that it too would have this advantage.

Claim 56 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hogan (6,569,191) in view of Stack (WO 91/17789) and Cotterman et al. (2002/0153511) as applied to claim 1 above, and further in view of Turnlund et al. (5,629,077) for the reasons set forth in the paragraph above.

Claims 52-55 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hogan (6,569,191) in view of Stack (WO 91/17789) and Cotterman et al. (2002/0153511) as applied to claim 1 above, and further in view of Shaolian et al. (6,261,316). Hogan fails to disclose the claimed expansion force of 4, 6, 8 or 10 N or more. However, Shaolian et al. teach, in col. 14, lines 14-31, that the expansion force for a stent prosthesis should be as high as 8 lbs. (about 285 N) apparently in order to adequately expand the stent. It would have been obvious to provide the claimed expansion force for the Hogan stent so that it too would have this advantage.

Applicant's arguments filed April 21, 2004 have been fully considered but they are not persuasive. Stack teaches the combination of annealing and gamma-irradiating a stent as set forth above. As to the term "fenestrated", the openings 60

formed between the strands and spaced throughout the walled surface 58 in applicant's invention (figure 3 and [0049]) are considered to be fenestrations. Similarly, the openings formed between the strands and spaced throughout the walled surface of the Hogan stent are considered to be fenestrations.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Thaler whose telephone number is (703) 308-2981. The examiner can normally be reached Monday to Friday.

The fax phone number for the organization where this application or proceeding is assigned is (703)872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)308-0858.

mht
7/30/04

MICHAEL THALER
PRIMARY EXAMINER
ART UNIT 3731